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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Peter York, et al.

Serial No.: 10/070,093

Confirmation No.: 7330

Filed: July 31, 2002

For: Coformulation Methods and Their Products

Group Art Unit: 1615

Examiner: Eric E. Silverman

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence and the documents referred to as attached therein are being facsimile transmitted to the U.S. Patent and Trademark Office to the fax number indicated by the Examiner, namely, fax number 571-273-8300 to the attention of the named Examiner on the date below.

24th July 2006 _____
Date Signature

Dear Sir:

DECLARATION UNDER 37 C.F.R. §1.132

I hereby declare and state as follows:

1. That I, Peter York, until recently was employed as Chief Scientist of Nektar UK and am Professor of Physical Pharmaceutics at Bradford University (UK). My research has focused over recent years on particle formation using supercritical fluid technologies.

Therefore, at least half of the Salmeterol Xinafoate of Examples 10 and 16 of '221 is present in crystalline form.

7. That all statements made herein of my own knowledge are true and that these statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent resulting there from.

24th July 2006
Date

Signature,
Peter York, Ph.D., D.Sc.

Appendix

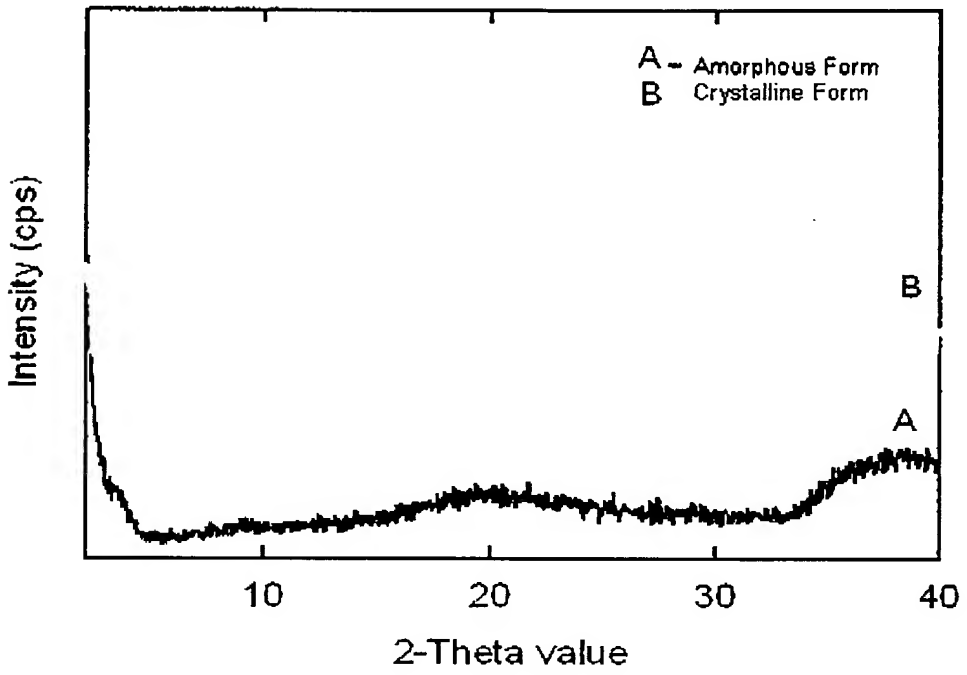

Figure 1

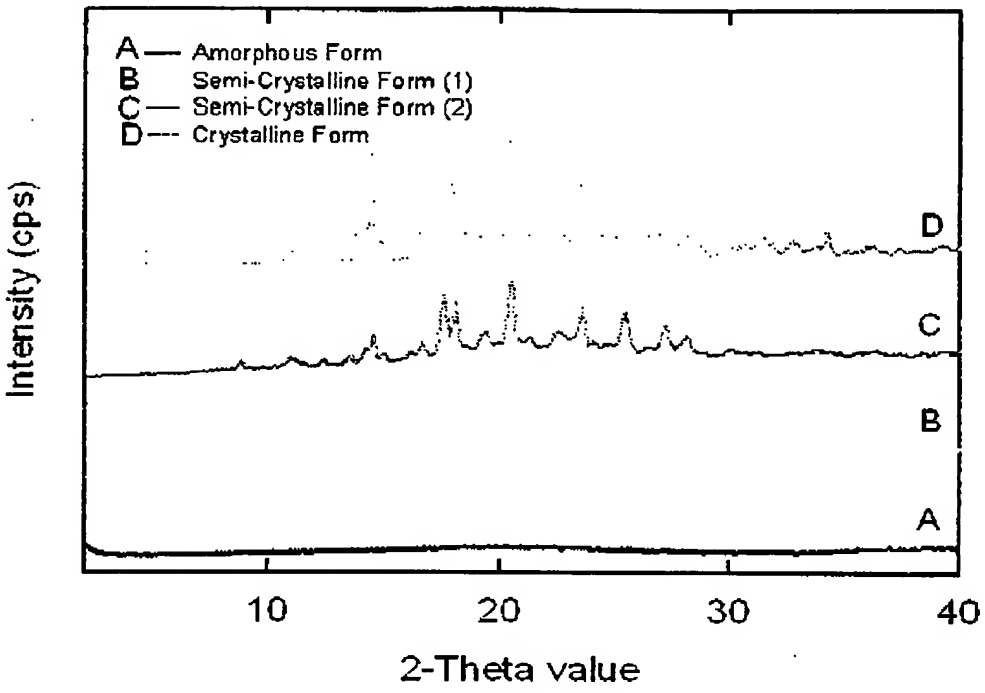
A — Amorphous Form
B Semi-Crystalline Form (1)
C — Semi-Crystalline Form (2)
D --- Crystalline Form
Intensity (cps)
D
C
B
A
10
20
30
40
2-Theta value

Figure 2

2. That I have a Ph.D. in Pharmaceutical Technology and a D.Sc. from the University of London.

3. That I am one of the inventors of United States Patent Application Serial No. 10/070,093, July 31, 2002, but have read the application (herein '093).

4. That I have read the specification of the International Application published under the Patent Cooperation Treaty as International Publication No. WO 95/01221, filed June 30, 1994 (herein '221).

5. That attached are two figures indicating the difference between amorphous and crystalline samples as measured by XRPD. Figure 1 shows a pure compound in both its amorphous (A) and crystalline (B) forms. As can be seen from the diffractogram, the crystalline form (B) exhibits various reflections (peaks) at different angles (2 theta) which indicate the reflection of the incident radiation at molecules in a fixed position in the crystal lattice. However, the amorphous form (A) does not show any reflections as the crystal lattice is no longer present, only random noise (amorphous halo) is obtained at all reflection angles. Figure 2 shows a compound co-formulated with a polymer in various stages from highly crystalline (D) to totally amorphous (A). In the transition from crystalline to amorphous (D to C to B to A) a broadening and disappearing of the crystalline reflections can be discerned until only an amorphous halo remains.

6. That the DCS/XRD data depicted in Figures 35, 36, 45 and 46 of '221 (relevant to Examples 10 and 16 in that document) indicate Salmeterol Xinafoate with a high degree of crystallinity. The DCS/XRD data depicted in '221 are closer in shape to the XRPD diffractogram of the Crystalline Form (D) or Semi-Crystalline form (2) (C) of Figure 2 of the Appendix.